510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

1. **Submitter:** L&K BIOMED Co., Ltd.
#1104, Ace High-end Tower 3 cha, 371-50, Gasan-Dong,
Geumcheon-gu, Seoul 153-803 Republic of Korea
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Contact Person: KiHyang Kim
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Date prepared: March 23, 2012

2. **Device Identification**

Proprietary Name	LEXUS Cervical Fixation System
Common Name	Spinal Fixation System
Product Code	MNI, KWP
Regulatory Class	II
Classification Name	Pedicle Screw Spinal System (21CFR888.3070) Spinal Interlaminal Fixation Orthosis (21CFR888.3050)

3. **Predicate or legally marketed devices which are substantially equivalent**
   - Spinal Concept Inc. / Nex-Link Spinal Fixation (K031985)
   - Aesculap Inc. / S4 Spinal Fixation (K050979, K060152)
   - Medtronic Sofamor Danek USA Inc. / VERTEX ™ Reconstruction System (K003780)
   - L&K BIOMED Co.,Ltd. / LEXUS Cervical Fixation System (K103414)

4. **Description of the Device**
The purpose of this 510(k) submission is to add reduction polyaxial screws and curved rods. The LEXUS Cervical Spinal Fixation System is a top-loading, multiple component, posterior (cervical-thoracic) spinal fixation system which consists of polyaxial screws, reduction poly screws, straight rods, curved rods, set screws, and hooks.
Materials: All products are made of titanium alloy (Ti-6Al-4V ELI/ in conformance with ASTM F136) approved for medical use.

5. **Intended use**

The LEXUS Cervical Fixation System is indicated for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Failed previous fusion
- Tumors

The implants are intended to provide stabilization as an adjunct to fusion when used with autogenous bone graft or allograft following the reduction of fractures/dislocations or trauma in the spine.

Hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1 –T3) spine.

The pedicle screws are limited to placement in T1 -T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine.

6. **Comparison of the technology characteristics of the device to predicate and legally marketed devices**

The LEXUS Cervical Fixation System is considered substantially equivalent to other legally marketed devices. They are similar in design, material, and indications for use and are expected to be equivalent in safety and effectiveness.

7. **Performance Data**

The LEXUS Cervical Fixation System is tested according to the ASTM F1717, specifically, Static and Dynamic Axial Compression, Static Tension and Static Torsion.

8. **Conclusion**

The LEXUS Cervical Fixation System is substantially equivalent to the devices referenced above and is therefore safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

L&K Biomed Co., Ltd.
% Ms. Ki Hyang Kim
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371-50, Gasan-Dong, Geumcheon-gu
Seoul, 153-803, Republic of Korea

MAY 2 3 2012

Re: K120879
Trade/Device Name: Lexus Cervical Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, KWP
Dated: May 03, 2012
Received: May 04, 2012

Dear Ms. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120879

Indications for Use

510(k) Number : K120879

Device Name : LEXUS Cervical Fixation System

Indications for Use :

The LEXUS Cervical Fixation System is indicated for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
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Prescription Use ____√___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120879